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10/807,362

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3954

7590 11/18/2008  
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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,362	<b>Applicant(s)</b> GLAUSER ET AL.	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 and 66-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The finality of the previous action is hereby withdrawn so that the following new rejections can be made of record. The indicated allowability of claims 43 and 44 is withdrawn in view of the newly discovered references to Wright et al. Rejections based on the newly cited references follow.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants have only described the polymer backbone in terms of its function. The specification gives only one envisioned polymer that meets this limitation and it is only named by its trade name. No additional description is provided to advise one of ordinary skill in the art which polymer structures meet the limitations of this claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50, 53, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 53 have been amended to read that the biocompatible polymer comprises “a non-fouling moiety, an anti-thrombogenic moiety, and a combination thereof”. The language is confusing because it is not clear if the non-fouling moiety and non-thrombogenic moiety are present separately in the polymer then also present in the polymer connected to one another, or if both the non-fouling moiety and non-thrombogenic moiety just have to be present in the polymer period. For the sake of application of prior art, the latter interpretation is used.

Claim 62 contains the trademark/trade name PolyAspirin™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In

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the present case, the trademark/trade name is used to identify/describe an unknown polymer and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilborn et al. (WO 2004/021976 – see IDS) in view of Koulik et al. (EP 0947205 – see IDS).

Hilborn et al. teach a medical device with a copolymer coating that includes a phospholipid within the biodegradable polymer chain (see abstract and page 7 lines 19-28). Stents are named as particular medical devices that are envisioned (see claims 15-16). Hilborn et al. also teach that the coatings are loaded with a biologically active agent (see claims 13-14). These coatings are taught for conferring biocompatibility and reduced protein adhesion to the device surface (see page 3 lines 14-28). Specifically a copolymer of polycaprolactone with phosphatidyl choline is taught (see page 11 lines 4-12). In addition to phosphatidyl choline, phosphatidyl serine and zwitterionic phosphatidyl ethanolamine are also taught as being equally suitable as phospholipids in the taught polymers (see page 8 lines 1-7). It is known that phosphoryl choline is contained within the structure of phosphatidyl choline, as is phosphoryl serine within phosphatidyl serine and phosphoryl ethanolamine within phosphatidyl ethanolamine. Therefore, a polycaprolactone-phosphatidyl serine polymer comprises both a biodegradable polymer and the claimed phospholipid phosphoryl serine. Hilborn et al. also teach that similar polymers have been made using non-biodegradable polymers

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that include polymethacrylates, polysulfones, polyethylenes and polystyrenes (see page 3 lines 14-20). Hilborn et al. do not specifically teach a biologically active agent attached to the polymer.

Koulik et al. teach a medical device with a biocompatible coating where a phosphoryl choline macromer, polybutylmethacrylate (acrylic polymer) and heparin are include in the same polymer (see abstract). The presence of the heparin, in addition to the phosphoryl choline is taught to reduce thrombogenicity (see paragraph 25; instant claims 59-60). Since both Hilborn et al. and Koulik et al teach phospholipid containing polymers as biocompatible coatings on medical devices, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Koulik et al. in the invention of Hilborn et al. to add heparin to their taught polymer and further improve the biocompatibility of their taught coatings (e.g. less thrombogenic). Thus in view of Hilborn et al. and Koulik et al., a medical device with a coating comprising a biocompatible polymer composed of heparin (bioactive), a degradable or non-degradable polymer backbone, and phosphoryl serine or phosphoryl ethanolamine would have been obvious. Therefore claims 43 and 59-60 are obvious over Hilborn et al. in view of Koulik et al.

Claims 43-49 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilborn et al. in view of Koulik et al. as applied to claims 43 and 59-60 above, and further in view of Wright et al. (U.S. Patent No. 6,273,913).

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Hilborn et al. in view of Koulik et al make obvious a medical device with a polymer coating composed of a biocompatible polymer that also includes within its structure a polycaprolactone or polybutylmethacrylate backbone, phosphoryl serine or phosphoryl ethanolamine, and an attached bioactive compound (see instant claims 46-49). Although this pair of references teaches the presence of both heparin bound to the surface and a biologically active within the coating, it does not teach bioactives other than heparin bound to the polymer.

Similar to Koulik et al., Wright et al. teach a polymer coating on a medical device where bioactive agents are chemically linked to the polymer coating. In particular, Wright et al. teach that rapamycin is bound to the polymer coating of a medical device to confer anti-restenotic properties to the device surface (see column 1 lines 8-13; instant claims 44-45). Since the binding of the bioactive to the polymer coating itself was a known method of delivering therapeutics from medical devices and Hilborn et al. teach that their coatings on stents, it would have obvious to one of ordinary skill in the art to bond rapamycin to the phospholipid containing biocompatible polymer coating so as to ward against restenosis in the device, as well as protein adhesion and thrombogenesis. Therefore claims 43-49 and 65 are obvious over Hilborn et al. in view of Koulik et al. and Wright et al.

Claims 43, 45, 50-61, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilborn et al. in view of Koulik et al. and Wright et al. as applied to



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claims 43-49 and 65 above, and further in view of Marchant (U.S. Patent No. 5,455,040).

Hilborn et al. in view of Koulik et al. and Wright et al. make obvious a medical device (stent) with a coating composed of a biocompatible polymer that also includes within its structure a polycaprolactone or polybutylmethacrylate backbone, phosphoryl serine or phosphoryl ethanolamine, heparin and rapamycin (see instant claims 43, 45, and 59-60). This modified reference does not explicitly teach the presence of a non-fouling moiety or the heparin being attached to the polymer via a spacer.

Marchant teaches medical devices with polymer coatings that are resistant to protein deposition and coagulation (thrombogenesis) (see column 3 lines 2-5). Similar to Hilborn et al. in view of Koulik et al. and Wright et al., Marchant also teaches heparin as an anti-thrombogenic agent attached to the polymer (see column 3 lines 14-15; instant claims 54 and 60). Marchant also teaches that the heparin is attached to the polymer via a spacer arm such that the surface can be non-thrombogenic without adversely affecting the bulk properties of the polymer coating (see column 3 lines 11-13 and 19-21). Additionally, the spacer is taught to be poly (ethylene oxide) (PEG) which provides a solvated surface for the device and lifts the heparin off the surface of the device (see column 3 line 65-column 4 line 7; instant claims 50-61 and 64). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the invention of Hilborn et al. in view of Koulik et al. and Wright et al. such that the heparin is attached to the polymer via a PEG spacer. This PEG

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spacer also serves as a non-fouling moiety. Therefore claims 43, 45, 50-61, and 64 are obvious over Hilborn et al. in view of Koulik et al., Wright et al. and Marchant.

Claims 43, 45, and 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilborn et al. in view of Uhrich et al. (U.S. PGPub No. 2004/0096476), Falatico et al. (U.S. PGPub No. 2001/0029351), and Wright et al.

Hilborn et al. teach a medical device with a copolymer coating that includes a phospholipid within the biodegradable polymer chain (see abstract and page 7 lines 19-28). Stents are named as particular medical devices that are envisioned (see claims 15-16). Hilborn et al. also teach that the coatings are loaded with a biologically active agent (see claims 13-14). These coatings are taught for conferring biocompatibility and reduced protein adhesion to the device surface (see page 3 lines 14-28). Specifically a copolymer of polycaprolactone with phosphatidyl choline is taught (see page 11 lines 4-12). In addition to phosphatidyl choline, phosphatidyl serine and zwitterionic phosphatidyl ethanolamine are also taught as being equally suitable as phospholipids in the taught polymers (see page 8 lines 1-7). It is known that phosphoryl choline is contained within the structure of phosphatidyl choline, as is phosphoryl serine within phosphatidyl serine and phosphoryl ethanolamine within phosphatidyl ethanolamine. Therefore, a polycaprolactone-phosphatidyl serine polymer comprises both a biodegradable polymer and the claimed phospholipid phosphoryl serine (see instant claim 43). In addition to caprolactone being a monomer in the polymer backbone, Hilborn et al. also teach other biodegradable monomers that form polyesters including lactide and glycolide (see page 7 lines 30-33). Hilborn et al. do not specifically teach a

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polymer backbone that degrades into pharmacologically active components that act in the process of restenosis or sub-acute-thrombosis and also do not teach that the biologically active agent is attached to the polymer.

Uhrich et al. teach a polyanhydride ester polymer that degrades into the anti-inflammatory salicylic acid (therapeutically active in sub-acute thrombosis, interpreted as equivalent to PolyAspirin™) (see example 1; instant claims 62-63). These polymers are taught used in implanted medical devices (see paragraph 12). In addition, Uhrich et al. also teach that other biologically active molecules can be included with these polymers and in particular, are covalently bound to these polymers (see paragraph 15).

Falatico et al. teach stents that are coated with a polymer coating that contains multiple drugs (see paragraphs 31 and 33). In particular, Falatico et al. teach the combination of anti-inflammatory agents with rapamycin in such a surface coating (see paragraph 62)

Wright et al. teach a polymer coating on a medical device where bioactive agents are chemically linked to the polymer coating. In particular, Wright et al. teach that rapamycin is bound to the polymer coating of a medical device to confer anti-restenotic properties to the device surface (see column 1 lines 8-13; instant claims 44-45).

In light of the teachings of Uhrich et al. and Falatico et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to use their salicylic acid producing polyanhydride ester polymer as the biodegradable polyester in the polymer taught by Hilborn et al. as a stent coating. This would yield a coating with a

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polymer that comprises phosphoryl serine or phosphatidyl ethanolamine and a backbone that degrades into pharmacologically active components that act in the process of restenosis or sub-acute-thrombosis. Also present in such a coating would be a biologically active agent. Since Uhrich teaches that any biologically agent can be present and bound to their polymers and Falatico et al. teach the combination of rapamycin with an anti-inflammatory compound in stent coatings as desirable for combating the body's response to stent implantation, it would have also been obvious to select rapamycin as the biologically active agent and have it bound to the polymer in the coating. This selection is further supported by the teachings of Wright et al. who particularly teach that rapamycin was known to be bound to polymer coatings on medical devices. Therefore claims 43, 45, and 62-63 are obvious over Hilborn et al. in view of Uhrich et al., Falatico et al., and Wright et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-45, 47-48, and 65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-9, and 11-14 of U.S. Patent No. 7,396,541 in view of Koulik et al. The claims of the patent and those of the instant application both teach a medical device with a coating where the coating is composed of polymers that contain in their chain a backbone, phospholipid-type molecule, heparin and a drug (bioactive). While the patent teaches phosphoryl choline as this phospholipid-type molecule, the instant claims teach others such as phosphoryl serine and phosphoryl ethanolamine. Koulik et al. teach the use of compounds within polymers that mimic the outer phospholipid bilayer to confer biocompatibility to medical device surfaces (see paragraph 29 and figure 1A). Although Koulik et al narrow in on phosphoryl choline, present in phosphatidyl choline, Figure 1A also demonstrates the presence of phosphatidyl ethanolamine (which contains phosphoryl ethanolamine) in particular in these membranes as well. Thus it would have been obvious to one of ordinary skill in the art to use phosphoryl ethanolamine instead of phosphoryl choline in the prodrug constructs taught by patent 7,396,541. Therefore claims 43-45, 47-48, and 65 are obvious over claims 1-4, 6-9, and 11-14 of U.S. Patent No. 7,396,541 in view of Koulik et al.

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Claims 43 and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 11/171111 in view of Koulik et al. The claim of the copending application and those of the instant application both teach a medical device with a coating where the coating is composed of polymers that contain in their chain a backbone, phospholipid-type molecule, and heparin (bioactive). While the copending application teaches phosphoryl choline as this phospholipid-type molecule, the instant claims teach others such as phosphoryl serine and phosphoryl ethanolamine. Koulik et al. teach the use of compounds within polymers that mimic the outer phospholipid bilayer to confer biocompatibility to medical device surfaces (see paragraph 29 and figure 1A). Although Koulik et al narrow in on phosphoryl choline, present in phosphatidyl choline, Figure 1A also demonstrates the presence of phosphatidyl ethanolamine (which contains phosphoryl ethanolamine) in particular in these membranes as well. Thus it would have been obvious to one of ordinary skill in the art to use phosphoryl ethanolamine instead of phosphoryl choline in the polymer taught by co pending application No. 11/171111. Therefore claims 43-44 are obvious over claim 12 of copending Application No. 11/171111 in view of Koulik et al.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

Applicants' arguments, filed August 29, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615  
16 November 2008